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EXAMINER

COUNTS, GARY W

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/937,730
Filing Date: January 08, 2002
Appellant(s): TAKAHASHI ET AL.

MAILED
FEB 08 2007
GROUP 1600

Amy E. Pulliam
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 17, 2006 appealing from the
Office action mailed January 24, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,284,194	Chu	09-2001
6,130,055	Nanbu et al.	10-2000
5,856,117	Uenoyama et al.	01-1999

5,912,139

Iwata et al.

06-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 12, 27, 31, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Nanbu et al (US 6,130,055) or Uenoyama et al (US 5,856,117).

Chu discloses an analytical device and method of making the device. Chu teaches that the device comprises a porous reaction membrane and at least one receptor immobilized in a limited region (col 1, lines 40-50) (reaction layer and reactive components). Chu teaches applying a surfactant (surface active agent) to the reaction membrane and allowing to dry (col 1, lines 55-67). Chu teaches that drying can be performed by air drying at room temperature or by warm air with good ventilation (col 9, lines 30-43). Chu teaches the surfactant can be a surfactant such as polyoxyethylene (23), polyoxyethylene sorbitan monolaurate or polyoxyethylene sorbitan monooleate (col 8). Chu teaches that all or most of the surface (col 5, lines 27-32, col 9) is exposed to the surfactant.

Chu differs from the instant invention in failing to teach the surface active agent comprises a surface active agent having sugar in a hydrophilic part.

Nanbu et al disclose surfactants (surface active agent) used in bioassays. Nanbu et al disclose that the surfactant (surface active agent) can be polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, lines 26-35). Nanbu et al teaches that the use of a surfactant improves the assay sensitivity.

Uenoyama et al disclose surfactants (surface active agents) used in bioassays.

Uenoyama et al disclose that the surfactant (surface active agent) can be polyoxyethylene (23), polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, line 59 – col 4, line 13).

Uenoyama et al disclose that this surfactant improves the assay sensitivity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute sucrose monolaurate surfactants (surface active agent) as taught by Nanbu et al for the surface active agent of Chu because Nanbu et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Nanbu teaches the equivalence of polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Nanbu et al in the method and device of Chu.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to substitute the n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate surfactants (surface active agent) as taught by Uenoyama

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et al for the surface active agent of Chu because Uenoyama et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Uenoyama et al teaches the equivalence of polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate and n-octyl-B-d-thioglucoside surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Uenoyama et al in the method and device of Chu.

With respect to claims 41 and 45 as recited in the instant claims. Chu teaches that drying can be performed by warm air in good ventilation. Therefore, Chu teaches drying moving air (wind) and thus Chu teaches wind drying as recited in the instant claims.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu in view of Nanbu et al or Uenoyama et al as applied to claims 5, 12, 27, 31, 41, 45, 53 and 60 and further in view of Iwata et al (US 5,912,139).

See above for teachings of Chu, Nanbu et al and Uenoyama et al.

Chu, Nanbu et al and Uenoyama et al differ from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). Iwata et al disclose that the components can be surfactants (col 6, lines 3-14 and col 10, lines 10-22). Iwata et al disclose that freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip, which provides high sensitivity and high accuracy measurement and excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate freeze drying as taught by Iwata et al into the modified method of Chu because Iwata et al teaches that freeze drying thoroughly removes water from the carrier and Iwata et al also teaches that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

(10) Response to Argument

Appellant argues that Chu fails to teach or suggest enhancing the permeability of the reaction layer, maintaining long-term permeability of the reactive layer, processing the entire reaction layer with the surface active agent, or employing a particular surface active agent which is solidified when dried and comprises a sugar in a hydrophilic part to prevent denaturing or deactivation of the reactive component. This is not found persuasive because it appears that the Appellant is only arguing the reference of Chu and not arguing the combination of Chu and Nanbu and Uenoyama et al references and absent evidence to the contrary the combination of Chu and Nanbu, and the

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combination of Chu and Uenoyama et al posses a surface active agent that is solidified when dried and would posses the advantages which applicant is arguing. Further, the fact that Appellant recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985)).

Appellant argues that the method of Chu does not teach or suggest processing the entire reaction layer with surface active agent, in order to enhance the permeability of the entire reaction layer. This is not found persuasive because Chu specifically teaches in column 9 that the entire reactive membrane is treated with surfactant. Appellant further argues that Chu fails to teach or suggest employing a surface active agent which comprises sugar in a hydrophilic part, in order to prevent deactivation of the reactive component. This is not found persuasive because Examiner has not relied upon Chu for teaching the limitation "sugar in a hydrophilic part" but rather has relied upon the secondary references for teachings that the use of surfactants with sugar in a hydrophilic part is known in the art. Further, to prevent deactivation of the reactive component is not recited in the instant claims and it appears that Appellant is arguing an advantage and as stated above the fact that Appellant recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985)).

Appellant argues that Nanbu et al fail to remedy the deficiencies of Chu.

Particularly, Appellant argues that Nanbu do not teach or suggest altering the teachings of Chu to process the entire reaction layer with the surface active agent. This is not found persuasive because as stated above Chu does teach processing the entire reaction layer (see above and col 9 of Chu). Appellant further argues that Chu fails to teach or suggest using a surface active agent which comprises sugar in a hydrophilic part and that although Nanbu et al. teach a surface active agent having a sugar in its hydrophilic part as an example of surface active agent which enhances the activity of the protease, most of the examples of surface active agents which enhance the activity of protease are those which do not have a sugar in their hydrophilic part. This is not found persuasive because of the rejections and reasons stated above.

Appellant argues that the Examiner does not provide a reason why one of ordinary skill in the art would select a surface active agent that is solidified when dried and comprises a sugar in a hydrophilic part. This is not found persuasive because as stated above and in the previous office action the Examiner has taken notice of the equivalence of sucrose monolaurate surfactant (contains a sugar in a hydrophilic part) (surface active agent) to polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate which can be used in the analytical device and the method of making the device of Chu and further, that the surfactants are equivalents in bioassays. Further, as stated above and in the previous office action Nanbu teaches that the use of the surfactant provides the advantage of improves assay sensitivity. (It is noted that this advantage is the same as the advantage disclosed by Applicant on page 10, lines 12

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and 13 "higher sensitivity"). Further, the selection of reagents can be affected by many factors such as the specific requirements of an assay, the availability of reagents as well as economic factors (i.e. the cost of reagents). Thus, the combination of Chu and Nanbu discloses a device and method of making the device and involves drying the device. The combination of Chu and Nanbu also teaches the device comprises a surfactant which would contain a sugar in the hydrophilic part and absent evidence to the contrary the combination of Chu and Nanbu possess a surface active agent that is solidified when dried and which is a would maintain long-term permeation, or prevention of denaturation or deactivation of specific protein by the function of sugar in the hydrophilic part in long term preservation thereby maintaining the performance of the specific proteins.

Appellant argues that there is no suggestion of the expectation of maintaining long-term permeation, or prevention of denaturation or deactivation of specific protein by the function of sugar in the hydrophilic part in long term preservation thereby maintaining the performance of the specific proteins. This is not found persuasive because the fact that Appellant recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985).

Appellant argues that Uenoyama et al fail to remedy the deficiencies of Chu. Particularly, Appellant argues that Uenoyama et al do not teach or suggest altering the teachings of Chu to process the entire reaction layer with the surface active agent. This

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is not found persuasive because as stated above Chu does teach processing the entire reaction layer (see above and col 9 of Chu).

Appellant argues that Uenoyama et al discloses 16 types of surfactants, which include n-octyl-B-D-thioglucoiside or sucrose monolaurate. Appellant states that there is no motivation to choose one of these particular surfactants from the many disclosed by Uenoyama et al. Therefore, whether these surfactants are equivalent to those taught by Chu is irrelevant. This is not found persuasive because as stated in the previous office action these surfactants provide improved sensitivity in assays (it is noted that this is one of the same advantages disclosed in the current application on page 10).

Further, as stated in the previous office action the selection to any known equivalent to replace the surfactants of Chu would be within the level of ordinary skill in the art and as also stated in the previous office action the selection of reagents can be affected by many factors such as the specific requirements of an assay the availability of reagents as well as economic factors (i.e. costs of the reagents).

Appellant argues that Uenoyama et al employ a surface active agent in order to enhance the solubility of a slightly soluble substrate and there is no slightly soluble substrate or organic solvent used in Chu and therefore there is no reason to employ a surface active agent which is intended to enhance the solubility of a slightly soluble substrate, as taught by Uenoyama et al. This is not found persuasive because the Examiner has not relied upon Uenoyama et al for the specifics of a reaction system but rather has relied upon Uenoyama et al for teaching that it is known in the art of bioassays that n-octyl-B-D-thioglucoiside (surfactant with sugar in hydrophilic part) or

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sucrose monolaurate (surface active agent with sugar in hydrophilic part) (same surface active agents as disclosed by Appellant on page 19, lines 21-22) is equivalent to surface active agents disclosed by Chu and that the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art.

Appellant further argues that the combination of Chu and Uenoyama et al does not teach or suggest enhancing preservation stability in order to preserve the reagent for the long term, or that the surface active agent enhances the preservation stability of the enzyme solution by protecting the enzyme by sugar in the hydrophilic part. This is not found persuasive because these limitations are not recited in the claims and further because the combination of Chu and Uenoyama would possess a surface active agent that is solidified when dried and would provide the advantages which Appellant argues.

Appellant argues that the teachings of Iwata et al. do not remedy the deficiencies of Chu in view of Nanbu et al or Uenoyama et al. This is not found persuasive because as stated above, it is the Examiner's position that Chu in view of Nanbu or Uenoyama et al is appropriate and reads on the instantly recited claims. Therefore, the rejection based on combination of Iwata et al with Chu, Nanbu and Uenoyama et al is maintained and reads on the instantly recited claims.

(11) Related Proceeding(s) Appendix

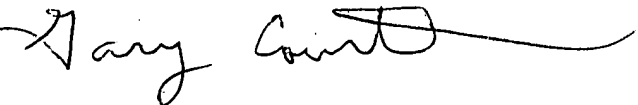
No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gary Counts
Examiner
Art Unit 1641



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